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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/279,275	07/22/94	WEINER H	101016104US1

HM12/0104

DARBY & DARBY
805 THIRD AVE.
NEW YORK NY 10022

EXAMINER	
VANDER VEGT, F	

ART UNIT	PAPER NUMBER
1644	62

DATE MAILED: 01/04/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
08/279,275	Weiner et al
Examiner	**Group Art Unit**
F. Pierre VanderVegt	1644

☒ Responsive to communication(s) filed on *Sep 30, 1999*.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *three* month(s), ~~or thirty days, whichever is longer,~~ from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1, 9, 11-13, 15, and 20-26* is/~~are~~ pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1, 9, 11-13, 15, and 20-26* is/~~are~~ rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). *31, 45*

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

This application is a file-wrapper-continuation of application S.N. 07/460,352, which is a continuation-in-part of application S.N. PCT/US88/02139, which is a continuation-in-part of application S.N. 07/065,734.

Claim 2 has been newly canceled.

Claims 1, 9, 11-13, 15 and 20-26 are currently pending in this application.

Reiterated claims 9, 11-13, 15 and 21-26 have not been entered nor considered since the claims have not been amended and the original claims 9, 11-13, 15 and 21-26 are still pending in the application. Reiterated claims 16-18 have not been entered nor considered since the claims were earlier canceled. It is suggested that, in the future, the amendments only address the claims to be amended and new claims and not to include any unamended or canceled claims, as their reiteration may cause confusion and typographical errors may result in the inadvertent introduction of new matter. If Applicant so desires, Applicant might consider appending a listing of all "currently pending claims" as an appendix to the rear of future responses.

1. The Examiner and Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Examiner F. Pierre VanderVegt of Group Art Unit 1644.

Transitional After Final Practice

2. Since this application is eligible for the transitional procedure of 37 CFR 1.129(a), and the fee set forth in 37 CFR 1.17(r) has been timely paid, the finality of the previous Office Action is hereby withdrawn pursuant to 37 CFR 1.129(a). Applicant's **second submission** after final filed on September 30, 1999 has been entered.

3. In view of the amendment filed September 30, 1999, only the following rejections are maintained.

Claim Rejections - 35 U.S.C. § 112

4. Claims 1, 9, 11-13, 15 and 20-26 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicant's arguments filed September 30, 1999 have been fully considered but they are not persuasive.

Applicant contends that Applicant has included evidence of enablement with the response filed September 30, 1999, however no such evidence can be found, only Applicant's continued argument. Applicant makes a series of statements but fails to substantiate them with citations pertaining to the appropriate art or with an expert affidavit. Accordingly, the arguments can not be considered evidence and the rejection stands for the same reasons stated previously in paper #56, mailed August 25, 1998.

5. **The following is a new ground of rejection.**

Claim Rejections - 35 U.S.C. § 112

6. Claims 1, 9, 11-13, 15 and 20-26 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Briefly, the claims are drawn to the treatment of autoimmune disease by oral or enteral immunization of a mammal with an autoantigen specific for the autoimmune disease being treated or an autoimmune response suppressive fragment thereof. The effectiveness of treating a response to an autoantigen is dependent on several factors, the most critical of which is whether the therapy can be used to treat an ongoing autoimmune response or whether it is only effective prophylactically (Tisch et al, U on form PTO-892, page 437, column 2, last paragraph in particular). Typically, an autoimmune disease is diagnosed only after significant tissue damage

has already occurred. Administration of antigen after pathogenic T cells have been activated may have an exacerbating effect on the disease, rather than a tolergenic one. Another problem during the treatment of autoimmune diseases is determinant spreading during the course of the disease. The Tisch et al reference also teaches that "the high degree of specificity required for the process of clonal deletion/anergy may be limiting when dealing with diseases such as MS, IDDM, and RA, in which there are responses to several autoantigens [...] and the critical inciting autoantigen(s) is not known" (page 437, third full paragraph of column 3 in particular). The breadth of Applicant's claims are such that they include treatment of autoimmune diseases with peptides which have not been characterized, on the basis of terming them "autoimmune response suppressive fragments." The claims confer no degree of specificity with which one of skill in the art could relate the treating peptide with a particular condition. Therefore the art would predict that it would be counterproductive to treat autoimmune disease patients with autoantigens or fragments, as such treatment would more likely than not exacerbate the ongoing immune response. The autoimmune diseases encompassed by the claims each have etiologies which are different from the others, each has different target autoantigens, and the risk of incidence of each of these is associated with a unique human lymphocyte antigen haplotype. Further there has been no disclosure of the autoantigens which are associated with immune attack in each of these conditions. Further, the working examples provided in the specification discloses only the prophylactic treatment of otherwise normal animals for a set time period prior to the occurrence of autoimmune events which are the result of a known initiating antigen. The artisan is not provided sufficient information by the instant specification in order to practice the method of the instant claimed invention over a long-term course for treatment of an ongoing autoimmune disease and may result in exacerbation rather than relief.

Pharmaceutical therapies are unpredictable for the following reasons; (1) the protein may be inactivated before producing an effect, i.e. such as proteolytic degradation, immunological inactivation or due to an inherently short half life of the protein; (2) the protein may otherwise not reach the target area because, for example, (a) the protein may not be able to cross the mucosa, (b) the protein may be adsorbed or absorbed by fluids, cells and tissues where the protein has no

effect; and (3) other functional properties, known or unknown, may make the protein unsuitable for in vivo use, i.e. may produce adverse side effects prohibitive to the use of such treatment. See MPEP 608.01(p).

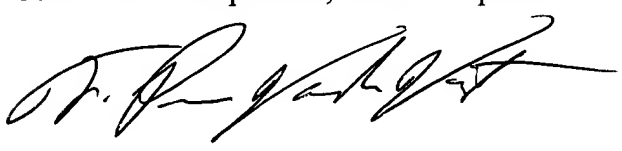
In view of the quantity of experimentation necessary, the limited working examples, the unpredictability of the art, the lack of sufficient guidance in the specification and the breadth of the claims, it would take undue trials and errors to practice the claimed invention and this is not sanctioned by the statute.

Conclusion

7. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which Applicant may become aware in the specification.

8. Papers related to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. Papers should be faxed to Group 1640 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The fax phone number for official documents to be entered into the record for Art Unit 1644 is (703)305-3014.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to F. Pierre VanderVegt, whose telephone number is (703)305-6997. The Examiner can normally be reached Tuesday through Friday and even-numbered Mondays (on 1999 365-day calender) from 7:00 am to 4:00 pm ET. A message may be left on the Examiner's voice mail service. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Ms. Christina Chan can be reached at (703)308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist, whose telephone number is (703)308-0196.



F. Pierre VanderVegt, Ph.D.
Patent Examiner
Technology Center 1600
January 3, 2000